DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 16 2002

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Marilyn A. Friedly
Director, Regulatory Affairs
PharmaForce, Inc.
1507 Chambers Road
Columbus, Ohio 43212

Re: Docket No. 02P-0127/CP1

Dear Ms. Friedly:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition dated March 25, 2002, requesting a determination that Phenergan (Promethazine Hydrochloride Injection USP) 25 Milligrams/Milliliter, 10 Milliliters (NDA No. 08-857) was not withdrawn from sale for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the Agency. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

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